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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,951	08/04/2003	Satishchandra P. Patel	M0025.0292/P0292	4472

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DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP

Edward A. Meilman

41st Floor

1177 Avenue of the Americas

New York, NY 10036-2714

EXAMINER

RUSSEL, JEFFREY E

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/632,951

Applicant(s)

PATEL, SATISHCHANDRA P.

Examiner

Jeffrey E. Russel

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1-22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3 sheets.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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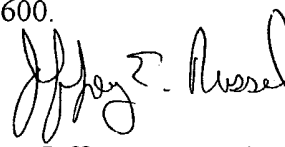
1. The originally-filed claims did not contain a claim numbered "14". Under 37 CFR 1.126, the originally-filed claims which were numbered "15" through "23" have been re-numbered as "14" through "22", respectively. Any future reference to these claims will use their re-numbered claim numbers. In any response filed to this Office action, Applicant is required to re-submit the claims with their re-numbered claim numbers. The dependencies of re-numbered claims 15 and 18 will have to be corrected accordingly.
2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
3. The disclosure is objected to because of the following informalities: At page 5, line 7, "(a)" should be changed to "(e)". Appropriate correction is required.
4. Claims 1-22 are objected to because of the following informalities: Claim 1 lists five components beginning with the letter "(b)". The absence of any component in the claim set designated "(a)" makes it unclear as to whether a component has been inadvertently omitted. It is suggested that the components in claim 1 be re-labeled as "(a)" through "(e)", respectively. Appropriate correction is required.
5. Claims 1-22 would be allowable if rewritten or amended to overcome the claim objection set forth in this Office action. The prior art of record does not teach or suggest a composition comprising a combination of a cyclosporin, a triglycerol monoester of a fatty acid, and a polyethylene glycol. Woo (U.S. Patent No. 5,589,455) teaches a combination of a cyclosporin and polyethylene glycol, but does not teach or suggest the presence of a triglycerol monoester of a fatty acid. Posanski (U.S. Patent Application Publication 2002/0099067) teaches a combination of a cyclosporin and a triglycerol monoester of a fatty acid, but teaches the presence

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of ethanol rather than polyethylene glycol. Stuchlik et al (U.S. Patent No. 6,106,860) teaches a combination of a cyclosporin and a triglycerol monoester of a fatty acid, but does not teach or suggest the presence of polyethylene glycol. There is not deemed to be motivation to combine the various individual components taught in the prior art in order to arrive at Applicant's claimed invention while still having a reasonable expectation that the resulting composition will form an emulsion having a particle size of less than 5 microns, as is claimed by Applicant.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

October 19, 2004